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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,508	06/05/2002	Bernd Dorken	101195-54	4142

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/869,508

**Applicant(s)**

DORKEN ET AL.

**Examiner**

Dave T. Nguyen

**Art Unit**

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,6-10 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 18-21 is/are allowed.
- 6) ☒ Claim(s) 16 and 17 is/are rejected.
- 7) ☒ Claim(s) 1-3 and 6-10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on December 30, 2003 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Claims 1, 16, 17 have been amended, claims 18-21 have been added by the amendment filed December 30, 2003.

Claims 1-3, 6-10, and 16-21 are pending.

The drawings dated December 30, 2003 has been reviewed and accepted by the examiner.

Both of the computer readable file and paper copy of the sequence listing, filed on January 9, 2004, have been entered. Thus, the previous objection to the sequence compliance has been withdrawn by the examiner.

However, the specification, particularly page 6, first paragraph (replacement paragraph amended April 2, 2003) is objected because the recitation of "nucleotide 453-2150 of the YB-1 promoter sequence, gene bank Acc. # X96666) is not accompanied by a SEQ identifier. An addition of "SEQ ID NO: 1" immediately after the "#X96666" is suggested.

Claims 1-3, 6-10 are objected because the all claims under US standard must

begin with article "A" (independent claim) or the article "The" (dependent claim).

Correction is required.

Claim 7 is objected because of the recitation "contain at least 3 enzyme restriction sites interfaces for restriction enzymes". The recited "interfaces" is grammatically incorrect when the recitation is read as a whole. Perhaps "interfaced" or "specific" would obviate the objection. Clarification is requested.

Claim 9 in the latest claim amendment is further objected because of misspelling errors. More specifically, "(Previously presented)" is misspelled. And the recitation of "wherein th " is misspelled. Correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Base claim 16 is indefinite because of the recitation of "it" on line 1. The recitation does not indicate *per se* as to what exactly is the element that "it" refers to. Should applicant intends to refer to the gene transfer vector of claim 1, then a change to "said gene transfer vector" is suggested.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 as currently amended is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly amended claim now embraces the claimed embodiments of the subject matter directed to a method of elevating the serum level of a transgene product comprising the use of the vector as claimed in claim 16 that is suitable for *in vivo* transgene expression. The specification neither an explicit or implicit support for the claimed subject matter. Thus, this is a new matter rejection. The specification, particularly pages 4 and 5, as a whole does not contemplate a **generic method of elevating the serum level of a transgene product by administering he claimed vector of claim 16**. The specification as a whole only provides written support for a method of enhancing an expression of a transgene product in proliferating tumor cells or chemo-resistant tumor cells. See pages 4 and 5 and abstract. Applicant refers to the

embodiment 2 or Figure 4 for the written support. However, a close review of embodiment 2 or Figure 4 only demonstrates an exemplified SCID mouse model, which shows a method of increasing the serum content of a human alpha antitrypsin (hAAT) gene product from proliferating hepatocytes, wherein the method comprises the use of adenoviral vectors that drive hepatocytes into proliferation, wherein the vectors contains an expression cassette having the Yb-1 promoter operably linked to the hAAT transgene. Figure 4 demonstrates the same. The claimed method as claimed in claim 17 neither recites the use of an adenoviral vector nor hepatocytes nor hAAT gene in the body of the claim. Given the fact that the specification as a whole is meant to contemplate a use of the claimed vector to drive specific expression of a transgene in proliferating tumor cells, see pages 4 and 5, the exemplified *in vivo* SCID mouse model is merely a demonstration of applicant's intended usage of the claimed vector to drive specific gene expression in proliferating tumor cells. The model is employed to simply prove the proliferation-specific activity of the YB-1 promoter. Note also that step(c), by simply reciting "measuring the serum level of the mammal at various times after administering the vector", further does not have any written support for such step. While the exemplified SCID mouse model contains a step of measuring the serum level of the hAAT gene product at the third day after the administering step, that step is not the same as step (c) as recited in claim 17. At best, the specification as a whole has a written support for a method of enhancing gene expression in tumor proliferating cells or chemo-resistant tumor cells, said method comprising administering the claimed vector of claim 16 to tumor proliferating cells or chemo-resistant tumor cells.

Applicant's response (page 2 of the response dated September 30 2003) has been considered by the examiner but is not found persuasive for the reasons set forth in the stated rejection.

Claims 18-21 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0184**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **703-872-9306**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen  
Primary Examiner  
Art Unit: 1632



DAVE T. NGUYEN  
PRIMARY EXAMINER